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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,811	08/21/2003	Christopher Marrs	NEU-5009	8041
27777	7590	09/03/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			MAYER, SUZANNE MARIE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,811	MARRS, CHRISTOPHER	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Jung et al. Jung et al. teach a one-liter composition that includes 300 mg of β -lactoglobulin, a range of ascorbic acid from 0-1 g and riboflavin (see p. 3848, Sample Preparation paragraph). Therefore the limitations of this instant claims have been anticipated and met by Jung et al.

3. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. Wang et al. teach the binding of retinoids to β -lactoglobulin. It should be noted that 'retinoid' is a generic term which includes the following specific molecules: retinal, retinoic acid, retinol and retinyl acetate (see Table 1., p. 1051). Wang et al. tested the binding capacity of β -lactoglobulin for all four specific types of retinoids by monitoring the specific fluorescence wavelength of the β -lactoglobulin after the addition of each retinoid. The experiment was performed by placing 3 ml of β -lactoglobulin into four cuvettes and adding 3 μ l of each type of retinoid (see p. 1048, 2nd paragraph

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(Determination of the apparent dissociation constants for bound retinoids)). In this particular way, Wang et al. ultimately produced compositions of β -lactoglobulin with retinoids, which is inclusive of the specific molecule retinol. These compositions subsequently meet the limitations as set forth in the instant claims and are rejected as having been anticipated by Wang et al.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferruzzi. Ferruzzi teaches a natural energy drink which comprises several ingredients which include: 1% whey protein, 0.01% ascorbic acid and 0.26% vitamin fortification premix (see p.7, example 1, paragraph [0078]). The vitamin fortification premix consists of several ingredients including vitamin A, vitamin C and vitamin E acetate (see p. 7, paragraph [0079]).

In considering how this composition relates to the instant claims, several definitions need to be clarified. By definition and according to PDR Health (see p.1, 2nd paragraph under Description) whey protein can be considered a generic term as it includes 70-80% α -lactoglobulin and β -lactoglobulin. The next three definitions have all been defined by Webster's 1913 Dictionary as found on-line. The definition of vitamin A is set-forth as: "Vitamin A is any of several related fat-soluble vitamins (such as retinol) essential for normal vision" (see p. 1 of on-line definition). The definition of vitamin C is set-forth as: "A vitamin that prevents

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scurvy. Also called ascorbic acid" (see p. 1 of on-line definition). The definition of vitamin E is set-forth as: "A fat-soluble vitamin that is essential for normal reproduction; an important anti-oxidant that neutralizes free radicals in the body". A synonym of vitamin E is defined as tocopherol (see p. 1 of on-line definition).

When considering the above definitions it is possible to directly relate them to the instant claims of this rejection. Claim 5 claims a composition of 0.01-1% of an oxygen labile active ingredient and 0.1-10% lactoglobulin. Claim 6 further limits claim 5 by defining the oxygen labile active ingredient as being any of the following: ascorbic acid, tocotrienol, hydroquinone, ubiquinone and dihydrolipoic acid. Therefore Ferruzzi's composition for the energy drink falls within the limitations of the claims, e.g., the drink contains 1% whey protein which contains lactoglobulins as defined above and 0.01% ascorbic acid. Claim 7 further limits claim 5 in claiming that the oxygen labile active agent is a retinoid. Wang et al., as stated above, teaches that retinoid is a generic term which includes the following specific molecules: retinal, retinoic acid, retinol and retinyl acetate (see Table 1., p. 1051). Furthermore, as defined by Webster's dictionary as stated above, retinol is also known as Vitamin A. Once again, Ferruzzi's energy drink composition meets the limitations of these claims since the composition also includes Vitamin A at 0.26%.

5. The same rationale is used for the claim rejections for claims 9-16.

However, claim 9 has two additional ingredients in the composition, on top of lactoglobulin and an oxygen labile active ingredient, as compared to claim 5.

These ingredients are claimed as an isoascorbic acid derivative and a tocopherol

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derivative. Claim 10 further limits claim 9 by stating that the oxygen labile active ingredient is 0.001-20%, the isoascorbic acid derivative is .001-0.5%, the tocopherol derivative is 0.1-1% and the lactoglobulin is 0.1-10%. Therefore Ferruzzi's composition for the energy drink falls within the limitations of the claims, e.g., the drink contains 1% whey protein which contains lactoglobulins as defined above, 0.01% ascorbic acid which by definition can be deemed as being an isoascorbic acid derivative (N.B. A derivative is defined as a chemical substance related structurally to another substance and theoretically derivable from it). In the same rationale, a tocopherol derivative would be vitamin E acetate. As defined above, tocopherol is a synonym for vitamin E and vitamin E acetate can be derived from vitamin E. Claim 12 and 15 further limits claims 9 and 10, respectively, in claiming that the oxygen labile active agent is a retinoid. Wang et al., as stated above, teaches that retinoid is a generic term which includes the following specific molecules: retinal, retinoic acid, retinol and retinyl acetate (see Table 1., p. 1051). Furthermore, as defined by Webster's dictionary as stated above, retinol is also known as Vitamin A. Once again, Ferruzzi's energy drink composition meets the limitations of these claims since the composition also includes Vitamin A at 0.26% in addition to 1% whey protein (lactoglobulin), ascorbic acid 0.01% and a tocopherol derivative (vitamin E acetate) which is also at 0.26%.

Therefore the energy drink composition as taught by Ferruzzi is a composition which meets the limitations of the instant claims and thus are rejected.

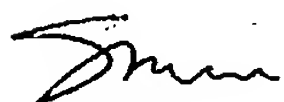
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Conclusion

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Friday from 8.30am to 5.00pm.

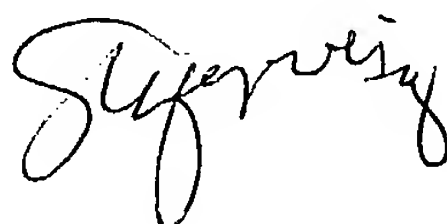
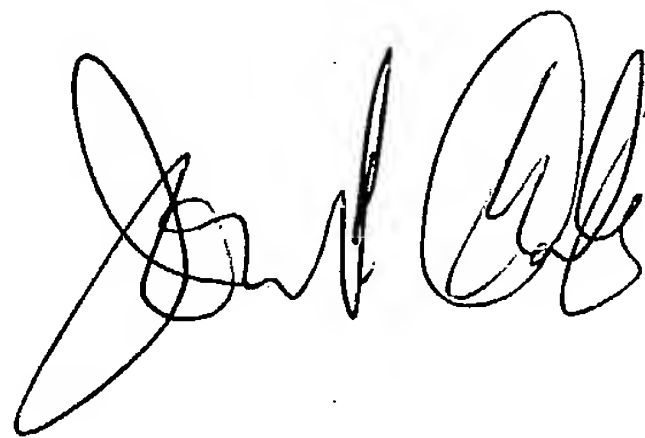
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SMM

24 August, 2004



Jon P. Weber, Ph.D.
Primary Examiner